

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Policy and Operations

4 (Amendment)

5 907 KAR 1:350. Coverage and payments for organ transplants.

6 RELATES TO: KRS 205.520, 42 C.F.R. 447.53

7 STATUTORY AUTHORITY: 194A.030(2), 194A.050(1), 205.520(3)

8 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family
9 Services has responsibility to administer the Medicaid Program. KRS 205.520(3) em-
10 powers the cabinet, by administrative regulation, to comply with any requirement that
11 may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid
12 funds. This administrative regulation establishes provisions related to Medicaid Pro-
13 gram [the] coverage of organ transplants for Medicaid recipients and related to Depart-
14 ment for Medicaid Services' reimbursement regarding organ transplants provided to
15 Medicaid recipients who are not enrolled with a managed care organization.

16 Section 1. Definitions. (1) "Department" means the Department for Medicaid Ser-
17 vices or its designee.

18 (2) "Emergency" means that a condition or situation requires an emergency service
19 pursuant to 42 C.F.R. 438.114(a).

20 (3) "Enrollee" means a recipient who is enrolled with a managed care organization.

21 (4) "Experimental" means that a procedure has not previously been proven effective

1 by the U.S. Food and Drug Administration in treating a patient's health condition.

2 (5) "Managed care organization" means an entity for which the Department for Medi-
3 caid Services has contracted to serve as a managed care organization as defined in 42
4 C.F.R. 438.2.

5 (6) "Medical necessity" or "medically necessary" means that a covered benefit is de-
6 termined to be needed in accordance with 907 KAR 3:130.

7 (7) "Nonemergency" means that a condition or situation does not require an emer-
8 gency service pursuant to 42 C.F.R. 438.114(a).

9 (8) "Recipient" is defined by KRS 205.8451(9).

10 Section 2. Prior Authorization. (1) Prior to coverage of an organ transplant to a recip-
11 ient who is not an enrollee, the transplant shall have been determined by the depart-
12 ment to be:

13 (a) Medically necessary; and

14 (b) Clinically appropriate pursuant to the criteria established in 907 KAR 3:130.

15 (2) The requirements established in subsection (1) of this section shall not apply to
16 an emergency service.

17 Section 3. General Coverage Criteria. A covered organ transplant shall meet the cri-
18 teria established in this section.

19 (1) A transplant surgeon's opinion shall conclude that failure to perform the trans-
20 plant would create a life-threatening situation.

21 (2) The patient's prognosis shall indicate that there is a reasonable expectation the
22 transplant will be successful and result in prolonged life of quality and dignity.

23 (3) The hospital where the transplant will take place shall:

1 (a) Have a staffed and functioning unit designed for and accustomed to performing
2 the planned organ transplant;

3 (b) Be accredited by the Joint Commission on Accreditation of Healthcare Organiza-
4 tions; and

5 (c) Be in good standing:

6 1. If it is an in-state hospital, with the Cabinet for Health and Family Services; or

7 2. If it is an out-of-state hospital, with that state's licensure authority.

8 (4) The physician performing the transplant shall be recognized as competent by the
9 medical community.

10 Section 4. Reimbursement for Organ Transplants. For an organ transplant provided
11 by a:

12 (1) Hospital to a recipient who is not an enrollee, the department shall reimburse as
13 established in:

14 (a) 907 KAR 10:825 through September 30, 2015; or

15 (b) 907 KAR 10:835 effective October 1, 2015.

16 (2) Physician to a recipient who is not an enrollee, the department shall reimburse in
17 accordance with 907 KAR 3:010.

18 Section 5. Noncovered Services. The department shall not approve a request for an
19 organ transplant if the requested transplant:

20 (1) Fails to meet the criteria of Sections 2 or 3 of this administrative regulation; or

21 (2) Is experimental in nature.

22 Section 6. Not Applicable to Managed Care Organizations. A managed care organi-
23 zation shall not be required to reimburse for an organ transplant according to this ad-

1 ministrative regulation.

907 KAR 1:350

REVIEWED:

Date

Lisa Lee, Commissioner
Department for Medicaid Services

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on April 21, 2015 at 9:00 a.m. in the Health Services Auditorium, Suite C, of the Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by April 14, 2015 five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until April 30, 2015. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, tricia.orme@ky.gov, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: (502) 564-7905, Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation Number: 907 KAR 1:350
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact: Stuart Owen (502) 564-4321

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes Medicaid program coverage provisions and requirements for organ transplants as well as Department for Medicaid Services (but not managed care organization) reimbursement provisions for organ transplants.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish Medicaid program coverage provisions and requirements for organ transplants as well as Department for Medicaid Services (but not managed care organization) reimbursement provisions for organ transplants.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing Medicaid program coverage provisions and requirements for organ transplants as well as Department for Medicaid Services (but not managed care organization) reimbursement provisions for organ transplants.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the authorizing statutes by establishing Medicaid program coverage provisions and requirements for organ transplants as well as Department for Medicaid Services (but not managed care organization) reimbursement provisions for organ transplants.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The amendment establishes that DMS will reimburse for organ transplants performed by a hospital as established in its inpatient hospital reimbursement administrative regulation - 907 KAR 10:830 rather than per its diagnosis-related group (DRG) inpatient hospital reimbursement administrative regulation – 907 KAR 10:825.
 - (b) The necessity of the amendment to this administrative regulation: The amendment is necessary as DMS is concurrently repealing 907 KAR 10:825 and promulgating 907 KAR 10:830 which is a new administrative regulation.
 - (c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statutes by updating a reference to another administrative regulation.
 - (d) How the amendment will assist in the effective administration of the statutes: The amendment will assist in the effective administration of the authorizing statutes by updating a reference to another administrative regulation.

- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: The amendment applies to all inpatient acute care hospitals that perform organ transplants. Currently, there are twelve (12) such hospitals participating in the Kentucky Medicaid program.
- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. No compliance action is mandated.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): This amendment imposes no cost on the regulated entities.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): No compliance action is mandated.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
 - (a) Initially: DMS anticipates incurring no additional cost as a result of the amendment.
 - (b) On a continuing basis: DMS anticipates incurring no additional cost as a result of the amendment.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and matching funds of general fund appropriations.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment. Neither an increase in fees nor funding will be necessary to implement the amendment to this administrative regulation.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: The amendment to this administrative regulation neither establishes nor increases any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used.) Tiering is not applied as the provisions apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 907 KAR 1:350

Agency Contact: Stuart Owen (502) 564-4321

1. Federal statute or regulation constituting the federal mandate. 42 U.S.C. 1396a(a)(30).
2. State compliance standards. KRS 205.520(3) states, “to qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect.”
3. Minimum or uniform standards contained in the federal mandate. Medicaid reimbursement for services is required to be consistent with efficiency, economy and quality of care and be sufficient to attract enough providers to assure access to services. 42 U.S.C. 1396a(a)(30)(A) requires Medicaid state plans to:
“. . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.”
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
The amendment does not impose stricter than federal requirements.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The policy is not stricter than the federal standard.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 907 KAR 1:350

Agency Contact: Stuart Owen (502) 564-4321

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) will be impacted by the amendment.
2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. 194A.030(2), 194A.050(1), 205.520(3), and 42 U.S.C. 1396a(a)(30).
3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? DMS anticipates no revenue being generated for the first year for state or local government due to the amendment to this administrative regulation.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? DMS anticipates no revenue being generated in subsequent years for state or local government due to the amendment to this administrative regulation.
 - (c) How much will it cost to administer this program for the first year? DMS anticipates incurring no additional cost as a result of the amendment.
 - (d) How much will it cost to administer this program for subsequent years? DMS anticipates incurring no additional cost as a result of the amendment.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: